

New Device to Test Potential Visual Acuity Compared With Gold Standard Potential Acuity Meter in Cataractous and Normal Eyes

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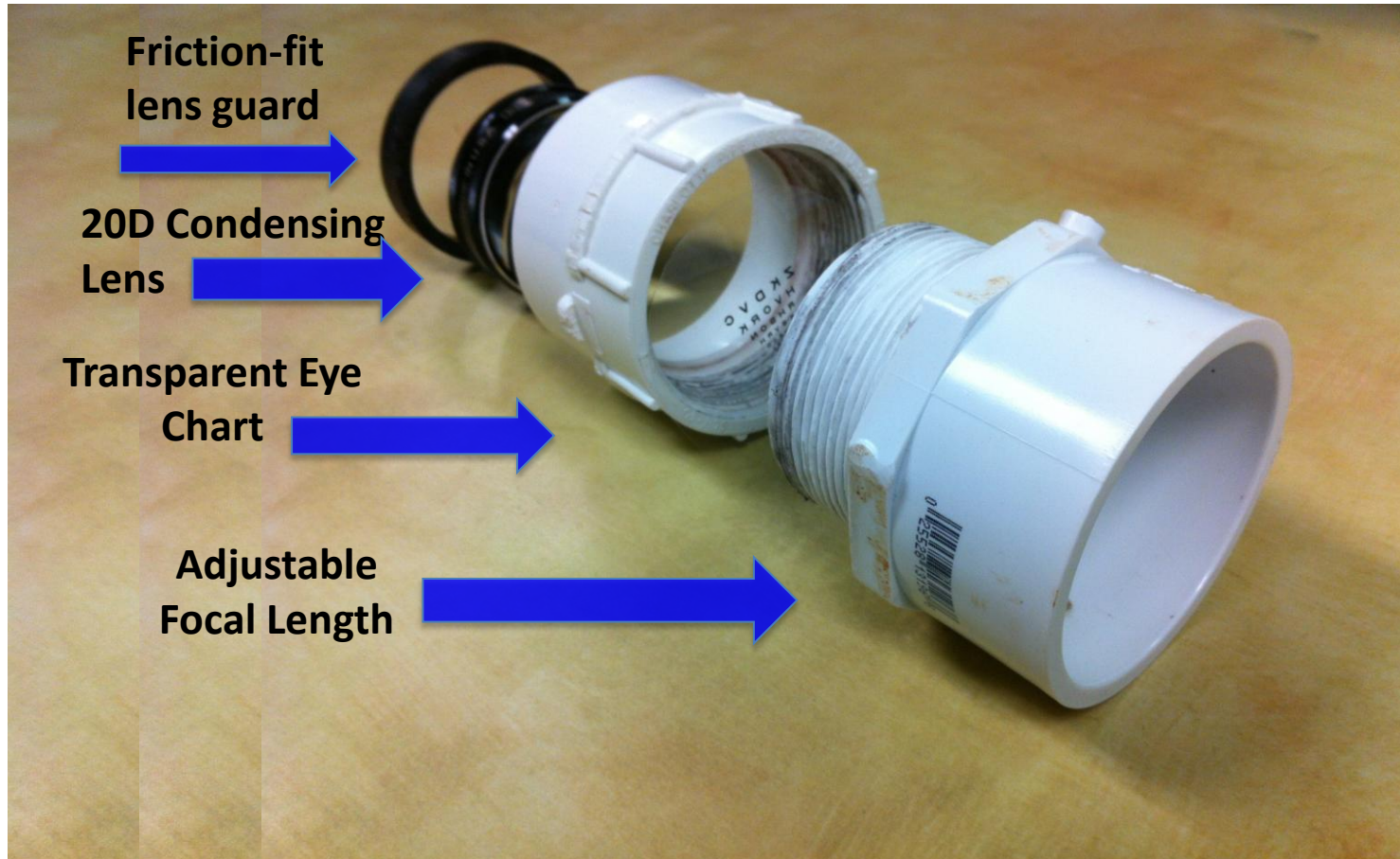
Financial Interest Disclosures: Author 1 has no financial interests in the subject matter of this poster. Authors 2 and 3 have U.S. Patent Pending 61/653,171 on the SCALE device.

Purpose

- Prospective comparison study of potential visual acuity measurement between the
 - new Kylstra-Richter SCALE and
 - the gold standard Guyton-Minkowski PAMin predicting visual outcome after cataract surgery

The Kylstra-Richter SCALE*

*Superior Clinical Assessment of Lens Effect



Device in Use



This new handheld device incorporates **indirect ophthalmoscopy** with a 20-diopter lens and a **transparent eye chart** to allow the physician to **directly visualize the macula** while projecting the eye chart onto it, to ensure that the patient is cooperative.

Physician's View: Simulated Fundoscopic Projection



Simulated retinal image from
<http://www.nei.nih.gov/photo/eyedis/ind>

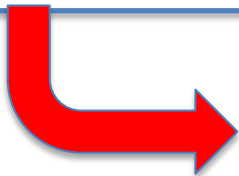
Background and Clinical Relevance

PAM

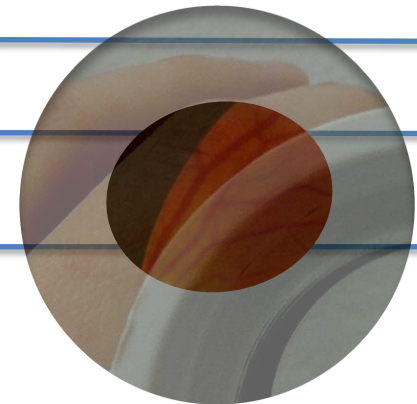


SCALE

• “Gold standard”	
• Cost (\$827 used¹)	• Parts <\$10 (+20 diopter lens)
• Bulky apparatus	• Compact, fits in pocket
• Physician cannot see the projected chart	• Physician can ensure chart is on macula
• Damaged machine is a permanent problem	• Ability to switch or replace charts easily
• Already owned by many practices	
• <u>Relies on patient cooperation</u>	



If failure, not known if due to true retinal/neurologic pathology or difficulties with equipment use



¹<http://www.opticalmarketplace.co.uk>

Methods

Exclusion criteria: any coexisting corneal or retinal pathology

1. Obtain acuity measurements

- Preoperative corrected distance visual acuity (**CDVA**) using a 20' projected Snellen wall chart
- Guyton-Minkowski **PAM** acuity
- Kylstra-Richter **SCALE** acuity
- Postoperative **CDVA** using a 20' projected Snellen wall chart

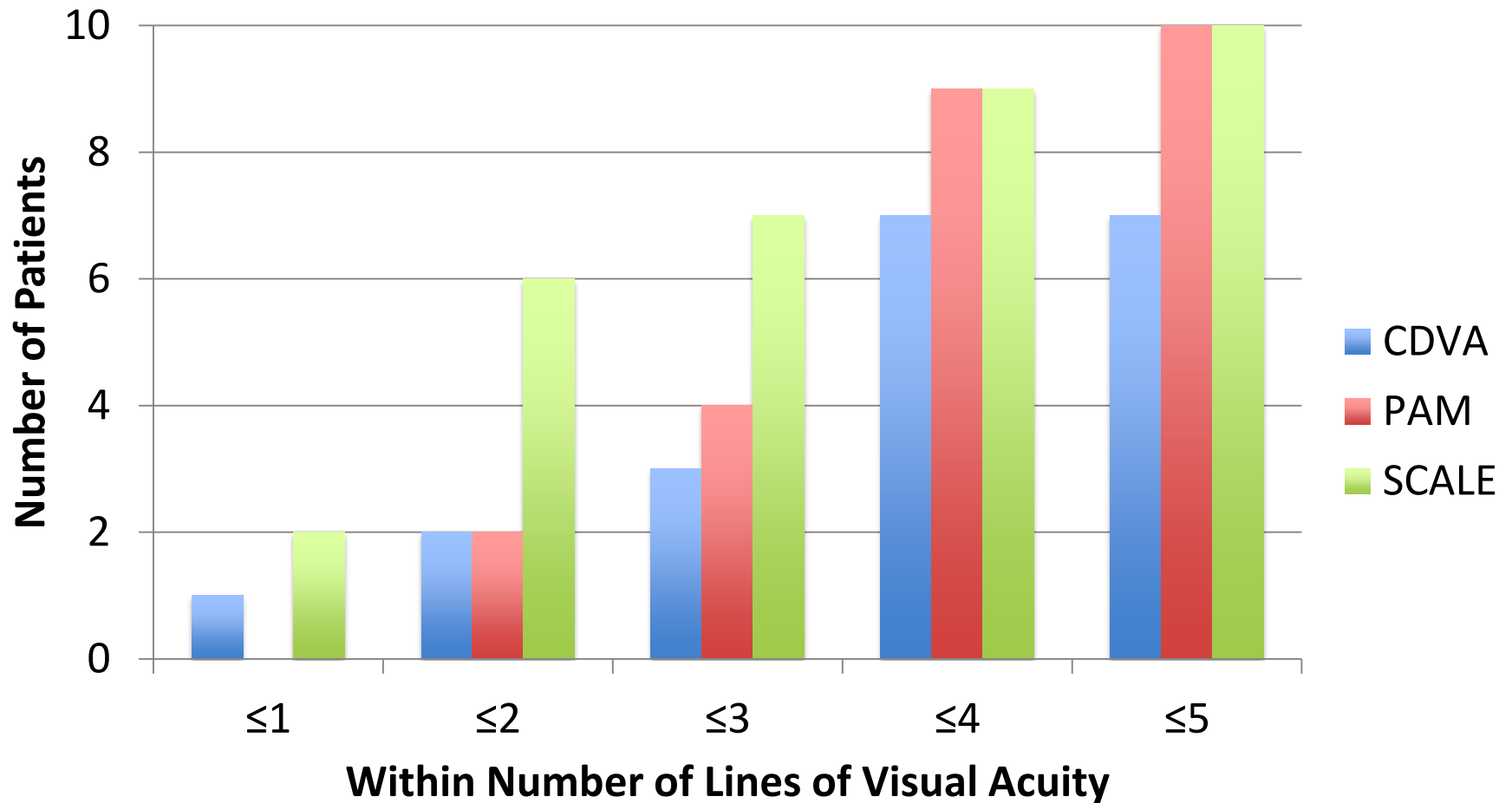
2. Convert visual acuities to logMAR

3. Compare PAM versus SCALE in predicting postoperative acuity in cataractous patients

Results

The average age of subjects was 66.9 years old (range 54-87), 50% males and 50% females.

Prediction of Visual Outcome



Results

		Does it predict postoperative acuity within 2 lines**?	
		+(yes)	-(no)
SCALE	+	6	4
PAM*	-	2	8

*gold standard

****Fischer exact test, P=0.17**

The average absolute inaccuracy of prediction for PAM was 0.29 lines (SD 0.11) compared to 0.20 (SD 0.14) for SCALE (P=0.07). Neither the PAM nor SCALE predictions overestimated postoperative CDVA.

Of note, non-cataractous eyes were able to see the PAM better than the SCALE. Our opinion is that maybe the intensity of the light of the indirect ophthalmoscope was undesirable to the clear lens patients, so they would not allow this test for as long.

Limitations and Future Directions

- Our biggest limitation was small sample size.
 - The current study is non-masked.
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- Future directions of this study will be devoted to **retinal and corneal pathology**, as well as **increasing sample size** to improve power.

Conclusion



In predicting post-cataract visual acuity, the **Kylstra-Richter SCALE** is a **portable, cost-effective** method, which is **non-inferior** to the current gold standard.

References

- Bach, M. Author Response: Numerical imputation for low vision states. IOVS. 47(3):1236-1240, 2006.
- Holladay, JT. Proper method for calculating average visual acuity. J Refract Surg. 13(4):388-91, 1997.
- Clinical trial registered at SCresearch.org #00016836